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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,243	12/10/2001	Dinesh O. Shah	5853-184US	4551
75	990 07/02/2003			_
Akerman, Senterfitt & Eidson, P.A.			EXAMINER	
Post Office Box 3188 West Palm Beach, FL 33402-3188		METZMAIER, DANIEL S		
			ART UNIT	PAPER NUMBER
			1712	4
			DATE MAILED: 07/02/2003	,

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>1</b>			_
	Application No.	Applicant(s)	
	10/016,243	PARMAR ET AL.	
Office Action Summary	Examiner	Art Unit	
	Daniel S. Metzmaier	1712	
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address	
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period v - Failure to reply within the set or extended period for reply will, by statute - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  Status	36(a). In no event, however, may a reply be ting within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).	
1) Responsive to communication(s) filed on 10 I	<u>March 2003</u> .		
2a)⊠ This action is <b>FINAL</b> . 2b)□ Th	is action is non-final.		
3) Since this application is in condition for allows closed in accordance with the practice under	ance except for formal matters, p <i>Ex parte Quayle</i> , 1935 C.D. 11, 4	rosecution as to the merits is 453 O.G. 213.	
Disposition of Claims	application		
<ul> <li>4)  Claim(s) 1-6 and 10-20 is/are pending in the a</li> <li>4a) Of the above claim(s) is/are withdraw</li> </ul>			
5) Claim(s) is/are allowed.	Wit from consideration.		
6)⊠ Claim(s) <u>1,3-5,10-15,19 and 20</u> is/are rejected			
7) Claim(s) 2.6 and 16-18 is/are objected to.	•		
8) Claim(s) are subject to restriction and/o	r election requirement.		
Application Papers	·		
9)☐ The specification is objected to by the Examine	r.		
10) The drawing(s) filed on is/are: a) acce	pted or b)⊡ objected to by the Exa	miner.	
Applicant may not request that any objection to th			
11) The proposed drawing correction filed on	_ is: a)□ approved b)□ disappr	oved by the Examiner.	
If approved, corrected drawings are required in re	•		
12) ☐ The oath or declaration is objected to by the Ex	caminer.		
Priority under 35 U.S.C. §§ 119 and 120			
13) Acknowledgment is made of a claim for foreign	n priority under 35 U.S.C. § 119(a	a)-(d) or (f).	
a) ☐ All b) ☐ Some * c) ☐ None of:			
1. Certified copies of the priority document			
2. Certified copies of the priority document			
<ul><li>3. Copies of the certified copies of the prior</li><li>application from the International But</li><li>* See the attached detailed Office action for a list</li></ul>	ıreau (PCT Rule 17.2(a)).		
14) ☐ Acknowledgment is made of a claim for domest	ic priority under 35 U.S.C. § 119	(e) (to a provisional application).	
<ul> <li>a) ☐ The translation of the foreign language prediction</li> <li>15)☐ Acknowledgment is made of a claim for domest</li> </ul>			
Attachment(s)			
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal	ry (PTO-413) Paper No(s) Patent Application (PTO-152)	
I.S. Patent and Trademark Office			_

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#### **DETAILED ACTION**

Claims 1-6 and 10-20 are pending. This action is responsive to the amendment filed March 10, 2003, Paper No. 6. Claims 7-9 were canceled by said amendment.

### Claim Rejections - 35 USC § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 2. Claims 3 and 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 3, it is unclear whether said oil varies from 0.001 to 5 wt/wt% of the oil phase or said oil varies from 0.001 to 5 wt/wt% of the microemulsion.

Claims 12-14 are indefinite because use is not a proper method step. While said claims have been amended to include the step of "providing", it is unclear how applicants are "using" said microemulsion, eg., as a topical coating, in vivo, as an adjuvant, as a active agent, etcetera.

## Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

<sup>(</sup>b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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### Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 6. Claims 1, 3-5, 15 and 19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Goddard et al, 4,704,220. Goddard et al (Table III) discloses a corn oil microemulsion employing 1 gram of corn oil, 1 gram of Tergitol NP4 (understood to be defined as in example 1A, column 11, lines 21-23), ethoxylated nonylphenol having an average of 4 ethoxy units, and 4 grams Tergitol 25L7, an ethoxylated linear alcohol having 12 to 15 carbon atoms and an average of 7 ethoxy units. Said combinations are combined with base fluid A from example 1. Base fluid A contains salts and ethylene glycol. The Goddard et al reference does not include a ionic cosurfactant in the compositions. The ethylene glycol

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in the Goddard et al composition is a glycol and not a primary short chain (C1 to C6) alcohol excluded from the instant claims.

In example 5, Goddard et al discloses the antifreeze is diluted 50:50 with tap water. The microemulsions claimed (dilutable) read on the corn oil emulsion of the Goddard et al reference. The aqueous microemulsion composition would have been inherent to the Goddard et al reference.

To the extent the Goddard et al reference <u>differs</u> from the claims in the actual dilution of the corn oil emulsion and the characterization thereof as a microemulsion, the Goddard et al reference (column 13, lines 60-68) teaches various oils may be employed including vegetable oil. Goddard et al (example 5) further teaches the compositions have a cloud point, which clearly indicates the existence of an optically clear solution.

7. Claims 10-11 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goddard et al, 4,704,220. Goddard et al discloses microemulsions as set forth above in the preceding rejection.

Goddard et al <u>differs</u> from the claims in the exemplified concentration of the oil and/or the surfactant.

Goddard et al (column 9, lines 20-35) teaches the emulsifier can be employed at 0.1 to 100 times the amount of oil employed. Goddard et al (column 4, lines 41-53) teaches the oil is employed at about 0.001 to about 5 wt% of the microemulsion.

It would have been obvious to one of ordinary skilled in the art at the time of applicants' invention to vary the concentrations of the Goddard et al reference within

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those taught as an obvious variation of the prior art disclosed compositions having utility as an antifreeze.

#### Allowable Subject Matter

8. Claims 2, 6, 16, 17 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record does not disclose microemulsion compositions employing nonionic alkyl phenol ethoxylated surfactants as a single surfactant in the absence of a primary short chain (C1 to C6) alcohol and in the absence of an ionic cosurfactant.

The prior art of record does not disclose microemulsion compositions employing nonionic alkyl phenol ethoxylated surfactants to make neem oil microemulsion in the absence of a primary short chain (C1 to C6) alcohol and in the absence of an ionic cosurfactant.

### Response to Arguments

10. Applicant's arguments with respect to claims 1-6 and 10-20 have been considered but are most in view of the new ground(s) of rejection.

#### Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel S. Metzmaier whose telephone number is (703) 308-0451. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Dawson can be reached on (703) 308-2340. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Daniel S. Metzmaier Primary Examiner

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DSM June 30, 2003